

RESET!

Consolidated Regulations and Guidelines

Companion to RESET14 1/4/18



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Other parts separated out to reflect how they will be tabled:

Part 2. Poisons Amendment (2018 Measures No. 1)

Part 3. Narcotics Drug Regulations (2018 Measure No. 1)

Part 4. Medical Cannabis Regulations Other Matters (2018 Measures No. 1)

1. Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)

The Therapeutic Goods Order No. 93 (Standard for Medical Cannabis) is confirmed as the manufacturing standard for medical cannabis listed in the Australian Register of Therapeutic Goods.

2. Guide to Good Manufacturing Practice for Medicinal Products (GMP)

For guidance medical cannabis is consider an API extracted from plant sources under these regulations.

3. Guideline: Record Keeping and Reporting Version 1.0, October 2016

For guidance this guideline applies to record keeping for medical cannabis cultivation and processing.

4. Guideline: Security of Medicinal Cannabis Version 1.0, October 2016

For guidance this guideline is in force, with some general specifications being more clearly defined in the Medical Cannabis Regulations Other Matters (2017 Measures No. 1) Instrument 2017

5. Guideline: Fit and Proper Persons and Suitable Staff

Version 1.0, October 2016

These guidelines provide clarification of the Narcotics Drug Regulations 2016, which in turn provide clarification of the Narcotic Drugs Act 1967. The changes here update the guidelines for the Regulation changes I propose to make to the Narcotics Drug Regulations 2017, so the two documents are consistent.

1. Natural Person (Convictions)

Mandatory requirement: The licence applicant must provide details of any conviction, at any time, of the applicant for an offence against a law of the Commonwealth, a State or Territory, or another country.

Replace “at any time” with “in the last 7 years”

2. Natural Person (Civil Penalties)

Mandatory requirement: The licence applicant must provide details of any civil penalties imposed, at any time, on the applicant under a law of the

Replace “at any time” with “within the last 7 years”

8. Natural Person (Previous business experience)

Mandatory requirement: The licence applicant must provide details of previous business experience.

Addition of “relevant to the application” at the end of this sentence.

9. Natural Person (Professional qualification breaches)

Mandatory requirement: The licence applicant must provide details (if holding any professional qualifications issued under a law of the Commonwealth, a state or a territory) of any disciplinary or other action that is being, or has been, taken against the applicant by a person or body that is empowered to take such disciplinary action.

Change “or has been” to “or has been within the last 7 years”

6. Fees for Medical Cannabis Applications under the Narcotics Drug Act 1967.

Measure to remove payment for services not rendered and replace it with a bond

The charges levied by the Office of Drug Control do not appear to be contained within a legislative instrument.

This regulation is designed to instruct the Office of Drug Control to adjust their charges as follows.

Remove

In addition to licence fees and inspection fees, there are statutory charges which are in place to cover non-direct cost recovery of activities associated with licences. This includes the conduct of unannounced inspections, administrative processing of minor operating procedure variations lodged by licence holders, and other activities need to maintain the licencing scheme.

The quantum of charge for a licence is as follows:

- for a medicinal cannabis licence - \$27,360 for each period of 12 months, or part of a period of 12 months, for which the licence is in force;
- for a commercial cannabis research licence - \$27,360 for each period of 12 months, or part of a period of 12 months, for which the licence is in force;
- for a non commercial cannabis research licence - \$27,360 for the period for which the licence is in force.

Replace

In addition to licence fees and inspection fees, there are statutory charges which are in place to cover non-direct cost recovery of activities associated with licences. This includes the conduct of unannounced inspections, administrative processing of minor operating procedure variations lodged by licence holders, and other activities need to maintain the licencing scheme. These charges require the payment of a bond against potential liability. The bond is to be paid upon successful license application and held until set against a charge or refunded should be license not be renewed. In the event of a charge occurring, the bond must be restored to the full amount within 30 days.

The quantum of the bond for a licence is as follows:

- for a medicinal cannabis licence - \$20,000;
- for a commercial cannabis research licence - \$20,000;
- for a non commercial cannabis research licence - \$20,000